

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

CELGENE CORPORATION,

Plaintiff,

v.

SUN PHARMA GLOBAL FZE, SUN  
PHARMA GLOBAL INC., SUN  
PHARMACEUTICAL INDUSTRIES, INC.,  
and SUN PHARMACEUTICAL  
INDUSTRIES LIMITED,

Defendants.

C.A. No. 2:19-cv-10099 (SDW) (LDW)

**REDACTED VERSION**

**ORAL ARGUMENT REQUESTED**

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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Defendants Sun Pharma Global FZE, Sun Pharma Global Inc., Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries Limited (collectively, “Sun” or “Defendants”) respectfully submit this memorandum in support of their motion to dismiss the April 16, 2019 Complaint of Plaintiff Celgene Corporation (“Celgene”) pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

## **I. Introduction**

On April 16, 2019, Celgene filed this patent infringement suit against Defendants, alleging that Sun’s filing of its Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) relating to lenalidomide capsules 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg, infringed United States Patent Nos. 7,977,357 (“the ’357 patent”), 8,193,219 (“the ’219 patent”), and 8,431,598 (“the ’598 patent”) (collectively the “Asserted Patents”) under the Hatch-Waxman Act (35 U.S.C. § 271(e)(2)) and under 35 U.S.C. §§ 271 (a), (b), and (c). Complaint ¶¶ 55-59, 64-67, 73-77 (D.I. 1).

As a matter of law, however, Section 271(e)(2) does provide any basis or authority for Celgene’s lawsuit against Defendants. The Hatch-Waxman Act, as codified in 35 U.S.C. § 271(e)(2)(A), establishes a “technical” or artificial act of infringement of those patents listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the “Orange Book”) *only* where an ANDA filer includes a certification that such a listed patent is invalid or will not be infringed by the proposed ANDA product (such a certification is referred to as “a Paragraph IV certification”). Here, Celgene did not list any of the Asserted Patents in the Orange Book, and Sun has not submitted any Paragraph IV certifications in its ANDA for the Asserted Patents. Therefore, Celgene’s claims lack subject matter jurisdiction under 35 U.S.C. § 271(e)(2)(A) and should be dismissed.

Celgene also included claims under 35 U.S.C. §§ 271(a), (b), and/or (c) based only on speculative allegations of possible future infringement. Complaint ¶¶ 57-59, 64-67, 75-77. It is axiomatic that the possibility of future infringement is not enough to trigger requests for damages or injunctive relief. Nor are such claims valid under the Declaratory Judgment Act because Celgene’s speculative allegations lack the required immediacy and reality to trigger an actual justiciable controversy. It remains uncertain if and when the FDA will grant the approval of Sun’s ANDA and it is even more uncertain if and when Defendants would be ready or able to commercialize or sell their proposed ANDA product if the ANDA was approved. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Because Celgene has failed to establish the existence of an actual controversy necessary for a declaratory judgment of infringement under 35 U.S.C. §§ 271(a), (b), and/or (c), any claims of infringement should be dismissed for lack of subject matter jurisdiction.

## **II. Background**

Under the Hatch-Waxman Act, a company seeking approval to market a generic pharmaceutical product may file an ANDA with the FDA, identifying a branded drug as the “reference drug” to expedite approval. *See generally Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 440-41 (D.N.J. 2006) (explaining Hatch-Waxman proceedings). The ANDA contains information describing the proposed generic drug product. 21 U.S.C. § 355(j)(2)(A). If the branded drug is associated with any patents in the FDA’s Orange Book, then the ANDA must contain a certification corresponding to each of those patents. One such certification is a so-called “Paragraph IV” certification, which certifies that the listed patent is invalid, unenforceable, and/or will not be infringed by the proposed ANDA product. 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV). The ANDA applicant submitting a Paragraph IV certification must give notice of such certification to the patentee. 21 U.S.C. § 355(j)(2)(B).

To enable the patentee to contest the Paragraph IV certification, the Patent Act creates a “technical” act of infringement: submission of the ANDA with a Paragraph IV certification. *See* 35 U.S.C. § 271(e). As the Supreme Court has noted, the purpose of this creation “is to enable the judicial adjudication upon which the ANDA . . . schemes depend.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Moreover, if the patentee sues within 45 days of receiving notice, the FDA withholds final approval until either thirty months have passed or the litigation has concluded, whichever occurs first. 21 U.S.C. § 355(j)(6)(B)(iii).

Defendants filed ANDA No. 211846 (“Sun’s ANDA”) seeking FDA approval to commercially market generic versions of Celgene’s 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID<sup>®</sup> drug products. Sun duly and properly notified Celgene of the ANDA filing, and that it contained a Paragraph IV certification stating that Sun’s proposed ANDA product did not infringe any claim of [REDACTED], which were listed in the Orange Book in association with REVLIMID<sup>®</sup>. *See* Wu Decl., Exhibit 1.<sup>1</sup> On July 13, 2018, Celgene filed a complaint against Defendants for infringement [REDACTED], a suit which is still pending. *Celgene v. Sun Pharm. Indus. Inc.*, C.A. No. 2:18-cv-11630 (D.N.J.).<sup>2</sup>

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<sup>1</sup> “Wu Decl., Exhibit \_\_” refers to exhibit attached to the Declaration of Huiya Wu in Support of Defendants’ Motion To Dismiss, which declaration was filed concurrently herewith.

<sup>2</sup> Celgene subsequently provided a Covenant Not To Sue Defendants for Infringement of the ’217 patent based on the filing of Sun’s ANDA. *Celgene v. Sun Pharm. Indus. Inc.*, C.A. No. 2:18-cv-11630, Celgene Corporation’s Covenant Not To Sue for Infringement of U.S. Patent No. 7,855,217 (D.N.J. January 22, 2019) (D.I. 50).

Nine months later, Celgene brought the present action, asserting three new patents that *are not listed in the Orange Book*. Wu Decl., Exhibit 1. In its new Complaint, Celgene alleged that Sun’s proposed ANDA product will infringe the Asserted Patents pursuant to the Hatch-Waxman Act under 35 U.S.C. § 271(e)(2) and that the future manufacture and sale of Sun’s proposed lenalidomide products will infringe the Asserted Patents pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c). Complaint ¶¶ 55-59, 64-67, 73-77. As of the time of Celgene’s lawsuit—and the filing of this motion—Sun’s ANDA has yet to be approved by the FDA. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. See Wu Decl.,

Exhibit 2.

### III. Legal Standards

Relief under Fed. R. Civ. P. 12(b)(6) is available where a complaint does not allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). A court will not “credit bald assertions or legal conclusions” cast in the form of factual allegations. *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002).

In addition, Fed. R. Civ. P. 12(b)(1) allows a party to move for dismissal of claims based on a lack of subject matter jurisdiction, either by challenging the jurisdictional allegations of the complaint or by asserting the absence of jurisdiction in fact, apart from any specific pleadings. *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). “When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a court attaches ‘no presumptive truthfulness’ to the allegations of the non-moving party, and ‘the

existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.” *Abraxis Bioscience, Inc. v. Navinta LLC*, C.A. No. 07-cv-1251 (JAP), 2008 WL 2967034, at \*3 (D.N.J. July 31, 2008). At all times, the plaintiff has the burden of proof that jurisdiction does in fact exist. *Mortensen*, 549 F.2d at 891.

A motion to dismiss for lack of ripeness is also properly brought pursuant to Fed. R. Civ. P. 12(b)(1). *Abraxis Bioscience*, 2008 WL 2967034, at \*2 (citing *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 341 (3d Cir. 2001)). A dispute is not ripe for judicial determination if it “rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Wyatt, Virgin Islands, Inc. v. Virgin Islands*, 385 F.3d 801, 806-08 (3d Cir. 2004) (internal citation omitted) (rejecting declaratory judgment complaint on ripeness grounds because “plaintiffs merely feared potential future administrative or judicial action”). Similarly, in any action for a declaratory judgment, the plaintiff has the burden to allege facts establishing subject matter jurisdiction and that, under all circumstances, there is a “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal citation omitted).

#### **IV. Argument**

##### **A. The Hatch-Waxman Act Does Not Authorize Suit for Infringement of Patents Not Listed in the FDA’s Orange Book for Which There Are No Paragraph IV Certifications**

It is black letter law that Section 271(e)(2) does not authorize a patent infringement suit against a proposed ANDA product unless the ANDA itself contains a Paragraph IV certification to a patent listed in the Orange Book. *Eisai Co. v. Mut. Pharm. Co.*, No. Civ. A. 06-3613(HAA), 2007 WL 4556958, at \*12 (D.N.J. Dec. 20, 2007) (citing *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (Fed. Cir. 2002)). It is “*the act of filing a paragraph IV certification with respect to a*

*patent*” alone that “creates a cause of action for patent infringement in the patent holder” under Section 271(e)(2). *Id.*; *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1326 (Fed. Cir. 2003) (stressing that the “artificial infringement” created under the Hatch-Waxman Act necessarily turns on the filing of a Paragraph IV certification). To maintain an action under Section 271(e)(2), it is therefore necessary for a plaintiff to allege both that the patents being asserted are listed in the Orange Book in connection with the plaintiff’s drug products *and* that the defendants have certified under Paragraph IV that the asserted patents are invalid or not infringed. *Eisai*, 2007 WL 4556958, at \* 14.

Here, contrary to Celgene’s cursory pleading that the “the patents-in-suit are listed in the . . . ‘orange Book,’” (Complaint ¶ 12), *none* of the Asserted Patents are listed in the Orange Book in connection with Celgene’s REVLIMID<sup>®</sup> drug products (or any other drug products). Orange Book, Patent and Exclusivity for: N021880 (REVLIMID<sup>®</sup>) [https://www.accessdata.fda.gov/scripts/cder/ob/patent\\_info.cfm?Product\\_No=005&Appl\\_No=021880&Appl\\_type=N](https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=005&Appl_No=021880&Appl_type=N).<sup>3</sup> Because the Asserted Patents were not so listed, Sun’s ANDA does not contain any certifications regarding the Asserted Patents, let alone Paragraph IV certifications stating that the Asserted Patents are

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<sup>3</sup> The Court may take judicial notice of material parts of the public record and documents that are central to Plaintiff’s claims and referenced in the Complaint, including the listing of patents within the FDA’s Orange Book. *See, e.g., City of Santa Clara v. Trump*, C.A. No. 17-CV-00485 (WHO), 2017 WL 1459081, at \*4 n.2 (N.D. Cal. Apr. 25, 2017) (“[C]ourts may judicially notice information and official documents contained on official government websites”); *In re Merrill Lynch & Co., Inc.*, 273 F. Supp. 2d 351, 356-57 (S.D.N.Y. 2003) (on 12(b)(6) motion, court may take judicial notice of: “(1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents ‘integral’ to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant’s motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint . . .”). Consideration of materials that are subject to judicial notice does not convert a motion to dismiss into a motion for summary judgment. *See Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 166 n.8 (2d Cir. 2000); *see also Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001); *Anderson v. Simon*, 217 F.3d 472, 474-75 (7th Cir. 2000), *cert. denied*, 531 U.S. 1073 (2001).

invalid or not infringed. For these reasons alone, Celgene’s claims under Section 271(e)(2) must be dismissed. *See Eisai*, 2007 WL 4556958, at \* 14 (holding that “to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question.”).

**B. Celgene’s Claims Based on Speculative Future Infringement Fail under Rules 12(b)(1) and 12(b)(6)**

**1. Celgene Fails To State a Claim of Action under Sections 271(a)-(c) of the Patent Act**

Celgene’s Complaint further alleges, without basis, support, or explanation, that the future manufacture, use, or sale of Sun’s ANDA product “will” infringe the Asserted Patents under Sections 271(a), (b), and (c).<sup>4</sup> Complaint ¶¶ 57-59, 64-67, 75-77. Yet such bare and speculative allegations are not sufficient to “state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570.

Section 271(a) makes an infringer out of anyone who “without authority makes, uses, offers to sell, or sells any patented invention, within the United States.” 35 U.S.C. § 271(a). Sections 271(b) and (c) create a cause of action against those who “actively induce[] infringement” and “[w]hoever offers to sell or sells . . . a component of” the patented invention, respectively. 35 U.S.C. §§ 271(b), (c). All three therefore require allegations of actual existing infringement. Yet Celgene makes no allegations that Defendants are *presently* engaged in any infringing manufacture, use, offer to sell, or sale of products that infringe any of the Asserted

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<sup>4</sup> Celgene cannot allege that the development of Sun’s proposed ANDA product qualifies as infringing activities because the Hatch-Waxman Act provides a “safe harbor” that protects any activities related to the preparation and filing of an ANDA against claims of infringement under Sections 271(a), (b), and (c). 35 U.S.C. § 271(e)(1); *Eli Lilly*, 496 U.S. at 678 (“the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement . . . with regard to use of his patented invention only for the purpose of obtaining premarketing approval.”).

Patents. Instead Celgene merely asserts that, at some undetermined point in the future, “Sun will infringe,” “will induce infringement of,” and “will contributorily infringe” one or more claims of the Asserted Patents. Complaint ¶¶ 57-59, 64-67, 75-77. By omitting any allegation that Defendants are presently engaged in infringing activities and only expressly alleging potential future infringement based upon conditions that may or may not occur, Celgene fails to state a proper claim for infringement under Sections 271(a)-(c) of the Patent Act. As such, Fed. R. Civ. P. 12(b)(6) requires dismissal of those counts.

Moreover, the highly cursory nature of Celgene’s pleading mandates dismissal. While it is true that under Federal Rule of Civil Procedure 12(b)(6), a court must generally accept as true the factual allegations of the defendant’s counterclaims, and construe all “reasonable inferences” in the light most favorable to the defendant, “[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action” fails to suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Instead, the “well-pled factual allegations” must be sufficient to demonstrate a *plausible* “entitlement to relief.” *Id.*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008).

Here, Celgene has done nothing but parrot the standard for infringement and declare without any analysis that Sun’s proposed ANDA product will infringe the Asserted Patents. Rather than alleging any facts that would support its claims of infringement, Celgene incorrectly claims that the analysis has already been done via the filing of a (non-existent) statement under Paragraph IV concerning the Asserted Patents and relies on that mistake for its infringement claims. *See* Complaint ¶¶ 52-53. But the Asserted Patents are *not* listed in the Orange Book in association with Plaintiff’s Revlimid® product, and Sun has not made any Paragraph IV

certifications corresponding to the Asserted Patents. Beyond Celgene’s incorrect argument regarding Orange-Book-listed patents and Paragraph IV certifications as to those patents, Celgene makes no effort to describe the Asserted Patents or their claims or analyze how Sun’s proposed ANDA products infringe the claims of the Asserted Patents. Instead, Celgene simply declares that Defendants “will infringe.” *Id.* ¶¶ 55-59, 64-67, 73-77. Such threadbare recitations of the elements of the relevant causes of action, conclusory statements of infringement, and easily disproven allegations do not suffice as a well-pleaded complaint and therefore must be dismissed. *See Straight Path IP Grp., Inc. v. Vonage Holdings Corp.*, C.A. No. 14-502 (JLL), 2014 WL 1266623, at \*2 (D.N.J. Mar. 26, 2014).

## **2. Celgene’s Claims under Sections 271(a)-(c) Are Inconsistent with Congressional Intent in Enacting the Hatch-Waxman Act**

Moreover, even if Celgene’s claims did not concern merely speculative future injuries, the claims under Sections 271(a)-(c) of the Patent Act should be dismissed as contrary to the intent of Congress in enacting the Hatch-Waxman Act. Specifically, Congress created an artificial act of infringement triggered by the filing of an ANDA with a Paragraph IV certification specifically because otherwise there could be no liability under Sections 271(a)-(c). That is, Section 271(e)(2) “provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction . . . when . . . the ANDA applicant was not making, using, or selling the patented product.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *Eli Lilly*, 496 U.S. at 678 (noting that “the purpose of [§ 271(e)(2)] . . . is to enable the judicial adjudication upon which the ANDA . . . schemes depend” by creating the “highly artificial” act of patent infringement--filing an ANDA); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (reiterating that § 271(e)(2) “creates case-or-controversy jurisdiction” before the product goes to market).

However, “[n]othing in the Hatch-Waxman Act appears to contemplate that a patentee, at the same time it pursues the § 271(e) action created for it by the Act, would also pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts.” *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2008 WL 5046424, at \*12-13 (D. Del. Nov. 24, 2008). “In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed.” *Allergan*, 324 F.3d at 1330. Courts, therefore, regularly decline to exercise jurisdiction over claims brought under Sections 271(a)-(c) when doing otherwise would “undermine” Congress’s policy in enacting the Hatch-Waxman Act. *Id.* at 938-39. Here, the Court should decline jurisdiction over Celgene’s claims under Sections 271(a)-(c).

**3. To the Extent That Celgene Seeks Declaratory Judgment, Such Claims Are Too Remote and Speculative and Lack Subject Matter Jurisdiction**

While Celgene does not expressly describe its claims under Sections 271(a)-(c) as seeking declaratory judgment, each indisputably seeks such a judgment as each demands redress for speculative events that have not yet occurred and an adjudication of rights attendant thereto. *See Shaheen v. HSBCBank*, 283 F.R.D. 344, 351 (E.D. Mich. 2012) (finding cause of action for “imminent future injury” to be a declaratory claim, even though “Plaintiff does not expressly reference the Declaratory Judgment Act in his complaint”); *see also Schilling v. Rogers*, 363 U.S. 666, 677 (1960). Moreover, Celgene invokes jurisdiction based on 28 U.S.C. §§ 2201 and 2202, which govern declaratory judgment jurisdiction. Complaint ¶ 14. However, regardless of whether declaratory judgment jurisdiction was explicitly invoked, any claims for declaratory judgment found in Celgene’s Complaint must be dismissed because they seek relief for acts that are too remote and speculative and lack subject matter jurisdiction.

The Declaratory Judgment Act provides that, “in a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). “Declaratory judgment jurisdiction may not be predicated on pure speculation.” *Rosuvastatin*, 2008 WL 5046424, at \*12-13, \*13 n.12. To meet the “actual controversy” requirement in a declaratory judgment action by a patent owner against an alleged future infringer, two elements must be present:

(1) the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a) (1982), or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

*Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990). These two elements correspond to the requirement that the alleged controversy must have sufficient “reality” and “immediacy” to be deemed an “actual controversy” to warrant the issuance of a declaratory judgment. *MedImmune*, 549 U.S. at 127; *see Eisai*, 2007 WL 4556958, at \*17.

There is nothing real or immediate about the highly contingent and long-distant events that would have to occur for a patent infringement claim based upon an ANDA filing to arise under Sections 271(a)-(c). In the context of a dispute over the development of a generic drug competitor, “a controversy will only materialize if the FDA approves the accused drug and if [the defendant] decides to market the drug.” *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 939 (N.D. Ill. 1995). Yet here, the FDA has not issued even tentative approval of Sun’s ANDA. Indeed, the date of such approval—if it even occurs—is unknown. Nor does Celgene’s Complaint allege or even make a general assertion that the FDA will “imminently” approve Sun’s ANDA. This is not a surprise: as a matter of law it is “impossible to know when the FDA

might make such a determination . . . .” *Intermedics Inc v. Ventritex Co Inc.*, 991 F.2d 808, at \*4 (Fed. Cir. 1993). [REDACTED]

[REDACTED] Given that time frame, the alleged controversy is necessarily *not* imminent. *See Eisai*, 2007 WL 4556958, at \*16-18.

Further, even if the FDA approved Sun’s ANDA in [REDACTED], Celgene’s claims of infringement necessarily require that Defendants also actually successfully launch a generic version to REVLIMID<sup>®</sup>. *See Abbott Labs.*, 934 F. Supp. at 938 (“[T]he fact that Defendant requested FDA approval of its generic version [] does not mean that Defendant will not change its course of actions and decide not to market the drug.”). Myriad events could occur in the coming years that might affect the decision to launch, including but not limited to a change in market conditions, the availability of raw materials, changes in manufacturing, the development of new and improved drugs, and changes in the managements of the parties. *Id.* at 938-939.

Consequently, Celgene’s Complaint does not raise a justiciable controversy that is “of sufficient immediacy and reality” to warrant a declaratory judgment. *MedImmune*, 549 U.S. at 127; *see also Eisai*, 2007 WL 4556958, at \*18 (dismissing declaratory judgment claim prior to FDA approval because “[a]t least until the ANDA is approved . . . the controversy is not sufficiently immediate”); *see also Abbott Labs.*, 934 F. Supp. at 938-39 (same). Therefore, this Court should dismiss all of Celgene’s declaratory judgment claims under 35 U.S.C. §§ 271(a)-(c) for lack of subject matter jurisdiction.

#### **4. The Court Should Decline Jurisdiction over Celgene's Declaratory Judgment Claims**

Even if Celgene's declaratory judgment claims were properly alleged—and they are not—this Court should nevertheless decline jurisdiction over them. District courts possess significant discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites. *See Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 n.3 (Fed. Cir. 2012).

As described above, Celgene's claims under Sections 271(a)-(c) are inconsistent with the Congressional intent underlying the Hatch-Waxman Act. *See Rosuvastatin*, 2008 WL 5046424, at \*13; *Takeda Pharm. Co. v. Mylan, Inc.*, C.A. No. 14-CV-00314 (LHK), 2014 WL 3845878 at \*8 (N.D. Cal. Aug. 1, 2014). Indeed, allowing Celgene to proceed with its claims under Sections 271(a)-(c) for potential future infringement activities would circumvent the Hatch-Waxman Act. This should not be permitted. Thus, even if Celgene had pleaded facts showing sufficient immediacy and reality to grant jurisdiction for a declaratory judgment (which it has not), this Court should still decline to exercise such jurisdiction. *See, e.g., Abbott Labs.*, 934 F. Supp. at 938-39 (refusing to exercise jurisdiction over non-271(e) claims so as to not “undermine” Congress's policy in enacting Hatch-Waxman).

#### **V. Conclusion**

For the foregoing reasons, Defendants respectfully request that this Court dismiss all counts of Celgene's Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

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Respectfully Submitted,

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